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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte STEVEN A. GOLDMAN and SU WANG

Appeal 2011-012422
Application 09/282,239
Technology Center 1600

Before TONI R. SCHEINER, ERIC GRIMES and STEPHEN WALSH, *Administrative Patent Judges*.

SCHEINER, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 from the final rejection of claims 25, 26, and 29-41 as anticipated or obvious, and of claims 42-44 as containing new matter. We have jurisdiction under 35 U.S.C. § 6(b).

STATEMENT OF THE CASE

Claims 25 and 42 are representative of the claimed subject matter:

25. An enriched or purified preparation of human mitotic oligodendrocyte progenitor cells, wherein the majority of the cells in the enriched or purified preparation differentiate into O4 positive oligodendrocytes, when cultured in PDGF, FGF2, and NT3, and further develop into galactocerebroside positive oligodendrocytes in the presence of 5% FBS/IGF-1, the mitotic oligodendrocyte progenitor cells are from a post-natal human, and a human cyclic nucleotide phosphodiesterase gene P2 promoter is transcriptionally active in the oligodendrocyte progenitor cells.

42. The enriched or purified preparation of claim 25, wherein 66.3± 6.8% of cells in the enriched or purified preparation mature into O4-IR oligodendrocytes when cultured in the presence of 5% FBS/IGF-1.

The Examiner rejected claims 42-44 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement (new matter).

In addition, the Examiner rejected claims 25, 26, and 29-41 under 35 U.S.C. § 102(e) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Rao,[1] as evidenced by Scherer.[2]

We reverse.

WRITTEN DESCRIPTION

According to the Examiner, the recitation "wherein 66.3 ± 6.8% of cells . . . mature into O4-IR oligodendrocytes" in claim 42 (and dependent claims 43 and 44) is new matter because "the only association that can be made with respect to 66.3 ± 6.8% is 'O4-IR cells'" (Ans. 4).

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[1] Rao et al., US 6,361,996 B1, March 26, 2002.

[2] Steven S. Scherer et al., *Differential Regulation of the 2',3'-Cyclic Nucleotide 3'-Phosphodiesterase Gene during Oligodendrocyte Development*, 12 NEURON 1363-1375 (1994).

"In order to satisfy the written description requirement, the disclosure as originally filed does not have to provide *in haec verba* support for the claimed subject matter at issue." *Purdue Pharma L.P. v. Faulding, Inc.*, 230 F.3d 1320, 1323 (Fed. Cir. 2000). Rather, the disclosure must convey with reasonable clarity to those skilled in the art that the inventor was in possession of the invention. *See id.*

The Specification teaches that oligodendrocytes are O4-positive (Spec. 19: 5). In addition, Example 6, which is entitled "P/hCNP2:hGFP^{+}-sorted Cells Matured Largely, but not Exclusively, into Oligodendrocytes," indicates that:

> The majority of CNP2-sorted cells developed and matured as oligodendrocytes. By 3 weeks after FACS, 74.1 ± 7.7% of these cells expressed oligodendrocytic CNP protein; a matched sample of sorted cells stained after 3 weeks *in vitro* for O4 yielded 66.3 ± 6.8% O4-IR cells, most of which co-labeled for the more mature marker galactocerebroside . . . Nonetheless, concurrent development of non-oligodendrocytic phenotypes was also noted after FACS purification, albeit at lower frequency than oligodendrocytes.

(*Id.* at 21: 21-30.)

We agree with Appellants that the phrase "66.3 ± 6.8% O4-IR cells" in Example 6, when read in context, refers to oligodendrocytes, as opposed to non-oligodendrocytes.

Accordingly, the rejection of claims 42-44 as failing to comply with the written description requirement is reversed.

ANTICIPATION/OBVIOUSNESS

Claims 25, 26, and 29-41stand rejected as anticipated by or, in the alternative, as obvious over Rao. Claim 25 is directed, in relevant part, to a preparation of human mitotic oligodendrocyte progenitor cells, wherein the majority of the cells in the preparation are capable of differentiating into oligodendrocytes under specified conditions.

The Examiner finds that Rao discloses "an isolated, pure . . . and homogeneous population of lineage-restricted oligodendrocyte-astrocyte precursor cells" (Ans. 5), specifically, "cell type 14 from figure 1 as shown in examples 7 and 15" (*id.* at 22). The Examiner acknowledges that all of Rao's examples use rat cells, rather than human (*id.* at 5), but finds that Rao anticipates the claimed "enriched or purified preparation of human mitotic oligodendrocyte progenitor cells" (*id.* at 6) because Rao discloses that "the invention encompasses all mammalian neuroepithelial stem cells" (*id.* at 5).

Alternatively, the Examiner takes the position that "[o]ne of ordinary skill in the art . . . would have been motivated to use the methods taught by Rao et al. to isolate an enriched or purified preparation of human mitotic oligodendrocyte progenitor cells from humans . . . to treat neurological disorders in humans" (*id.* at 7). According to the Examiner, a reasonable expectation of success comes from Rao, "who successfully isolated an enriched or purified preparation of mitotic oligodendrocyte progenitor cells from rat" (*id.*).

We will reverse this rejection. As acknowledged by the Examiner, none of Rao's working examples anticipate the claimed oligodendrocyte progenitor cells because Rao's examples all concern rat cells, rather than human. Second, Rao's Figure 1 does not represent actual cell preparations,

rather, it is a diagram that "presents a model for spinal cord differentiation" (Rao, col. 6, ll. 45-46) in an unspecified species, and simply "suggests that the multipotent precursors ([neuroepithelial] cells) generate differentiated cells (i.e. oligodendrocytes **18**, type 2 astrocytes **22**, type 1 astrocytes **24**, neurons **26**, and motoneurons **30**) through intermediate precursors" (*id.* at col. 6, l. 64 - col. 7, l. 1). In any case, progenitor cell type 14 is depicted as giving rise to oligodendrocytes and astrocytes in unspecified proportions, under unspecified conditions.

Finally, as for Rao's assertion that "[t]he invention encompasses all mammalian neuroepithelial stem cells" (Rao, col. 6, 29-30), it is true that "anticipation does not require actual performance of suggestions in a disclosure." *Impax Labs., Inc. v. Aventis Pharms. Inc.*, 468 F.3d 1366, 1382 (Fed. Cir. 2006) (quoting *Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc.*, 246 F.3d 1368, 1378 (Fed. Cir. 2001)). However, "those suggestions [must] be enabled to one of skill in the art." *Id.*

In a nut shell, the Examiner has not identified any evidence that establishes that a majority of cells in any of Rao's rat cell populations differentiate into O4 positive oligodendrocytes when cultured in PDGF, FGF2, and NT3, and further develop into galactocerebroside positive oligodendrocytes in the presence of 5% FBS/IGF-1.

Appellants, for their part, have provided evidence in support of their assertion that Rao's rat cells "are bi-potential astrocyte/oligodendrocyte progenitor cells that have a strong astrocytic bias" which "distinguishes them from the presently claimed oligodendrocyte progenitor cells, the majority of which mature into oligodendrocytes" (App. Br. 14.). Merely by

way of example, we note the second Declaration[3] of Dr. Mahendra S. Rao, wherein Dr. Rao asserts that the "cells in the '996 Patent's pathway to oligodendrocyte production are bi-potential astrocyte/oligodendrocyte progenitor cells that have [a] strong astrocytic bias" (2d Decl. ¶ 7), and "are in a less differentiated state than the oligodendrocyte progenitor cells of the present patent application" (*id.* at ¶ 6).

Accordingly, while we agree with the Examiner that it would have been obvious to use Rao's protocol to isolate human cell populations corresponding to Rao's rat cell populations, we agree with Appellants that the Examiner has not established that doing so would have resulted in a population of human cells with the properties required by the claims.

SUMMARY

The rejection of claims 42-44 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement is reversed.

The rejection of claims 25, 26, and 29-41 under 35 U.S.C. § 102(e) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Rao is reversed.

REVERSED

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[3] Declaration executed May 10, 2005, and submitted May 27, 2005 under the provisions of 37 C.F.R. § 1.132, by Dr. Mahendra S. Rao, a co-inventor of US Patent 6,361,996 to Rao et al. ("2d Decl.").